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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,620	12/11/2001	Stanley J. Wiegand	REG 334-A-US	1424

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EXAMINER

JUNG, WILLIAM C

ART UNIT PAPER NUMBER

3768

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,620	WIEGAND, STANLEY J.	
	Examiner	Art Unit	
	William Jung	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-7, 10, 13-15, 17-19, 22, 25, 26, 31 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-7, 10, 13-15, 17-19, 22, 25, 26, 31, and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed May 11, 2006 have been fully considered but they are not persuasive.

After further consideration of the applicant's argument, examiner respectfully disagrees. In regards to applicant's argument on 102(e) rejection, the applicant believes that the Li et al do not disclose imaging or targeting vasculature with molecule capable of detecting angiopoietin-2 nucleic acid or polypeptide. In response, examiner would like to further clarify that the imaging agents are linked to DTPA as described in Li et al where DTPA forms double ligand bonding of contrast agent with polypeptide, where polypeptide has affinity to blood vessel formation or to injured cite in the body (e.g. cite of inflammation due to injury, angiogenesis, etc.). This particular specificity of the contrast agent along with DTPA ligand with target specificity allows accumulation of the contrast agent to a desired location. Therefore, examiner maintains the rejection from the previous office action dated March 9, 2006 with changes in claims where claims 2, 3, 8, 9, 11, 12, 16, 20, 21, 23, 24, 27-30, 32, 36, and 37 are cancelled.

Claim Objections

2. Claim 19 is objected to because of the following informalities: Claim 19 depends on cancelled claims 2, 8, and 9. Examiner assumes that the claim 19 would depend on claims 1, 6, and 7 for the purpose of the examination. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 4-7, 10, 13-15, 17-19, 22, 25, 26, 31, and 33-35 are rejected under 35

U.S.C. 102(e) as being anticipated by *Li et al* (US 6,006,123).

Li et al anticipate all claimed features in claims 1-9 and 11-34.

Claims 1, 6, 7, and 22, 25, 26, 34, and 35: Li et al disclose a method for imaging tumor vasculature (i.e. angiogenesis) in a mammal or human, comprising a molecule capable of detecting Ang-2 nucleic acid or polypeptide coupled to an imaging agent (usually a double ligand bonding via DTPA), allowing the composition to be target specific to accumulate to a region of interest to detect the tumor vasculature via imaging the imaging agent. In addition, the method above includes coupling a therapeutic agent to the imaging agent to treat or kill tumor cells (col. 5, lines 8-32; col. 6, lines 12-28; col. 7, lines 10-61). Furthermore, Li et al's method above includes materials or kit to carry out the described procedures to image and treat the patient.

Claim 4: Li et al disclose that the imaging method above can be applied to imaging system consisting of scintillation or gamma camera (i.e. x-ray), PET, SPECT, and MRI.

Claims 5, 13-15, 17-19, 31, and 33: Li et al disclose that the method above includes imaging agent may be a radionuclide, chelate, anti viral proteins, monoclonal antibody, , receptor specific polypeptide chains, mRNA, and oligonucleotide to be used in mammal , and more specifically in human (col. 4, lines 29-34; col. 5, lines 23-32).

Claim Rejections - 35 USC § 103

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Li et al* as applied to claim 6 above, and further in view of *Klaveness* (US 6,261,537 B1).

Li et al substantially disclose all claimed features in claim 10. In regards to therapeutic compounds, Li et al is silent as to the therapeutic compound to treat the tumor includes from the group consisting of carboplatin, cisplatin, vincristine, methotrexate, paclitaxel, docetaxel, 5-fluorouracil, UFT, hydroxyurea, gemcitabine, vinorelbine, irinotecan, tirapazamine, and matrilysin. However, the use of these therapeutic compounds is well known in the art as demonstrated by Klaveness et al, where the therapeutic agents listed above are used with ultrasound imaging contrast agent to target the specific region of interest by tagging the contrast agent/therapeutic agent with affinity to inflamed or injured cite such as tumor vasculature as described by Li et al above. Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings Klaveness et al's therapeutic agent with Li et al's method to achieve the claimed invention.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


August 5, 2006


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